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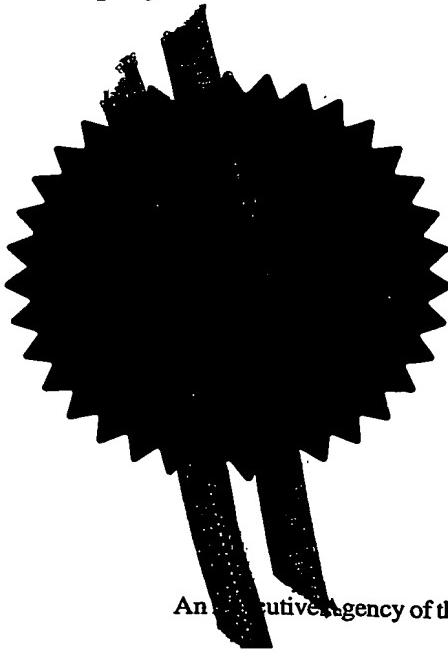
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24 JAN 2003

2. Patent application number
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Enfis Limited
Unit 4, Technium
Kings Road
The Docks
Swansea SA1 8PH
08154890002

Patents ADP number (*If you know it*)

If the applicant is a corporate body, give the country/state of its incorporation England and Wales

4. Title of the invention Method and device for treatment of skin conditions

5. Name of your agent (*If you have one*) Abel & Imray

"Address for service" in the United Kingdom to which all correspondence should be sent
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Claim(s) 7

Abstract 1

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Signature

Abel & Imray

Abel & Imray

Date

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Jim Pearson - (01225) 469914

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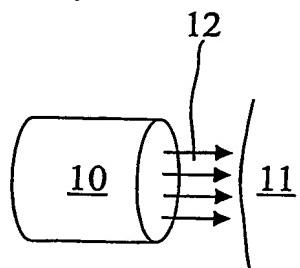


Fig 1

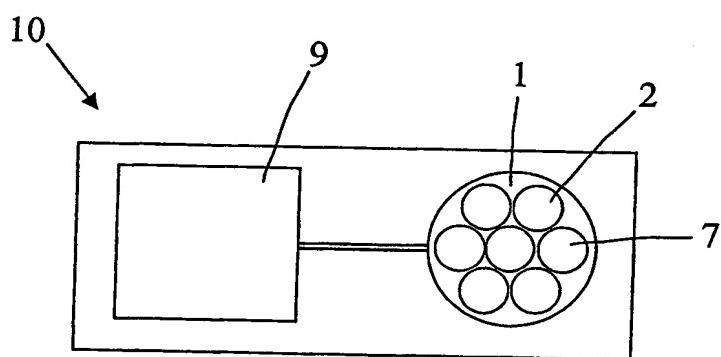


Fig 2

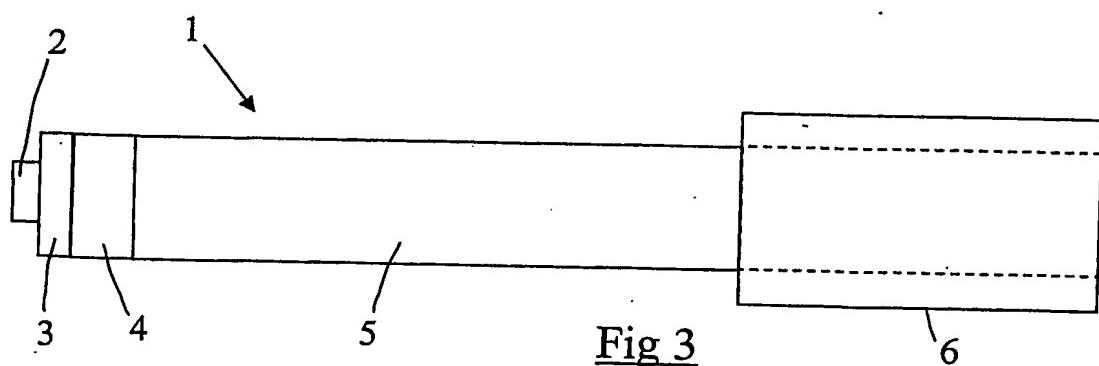


Fig 3

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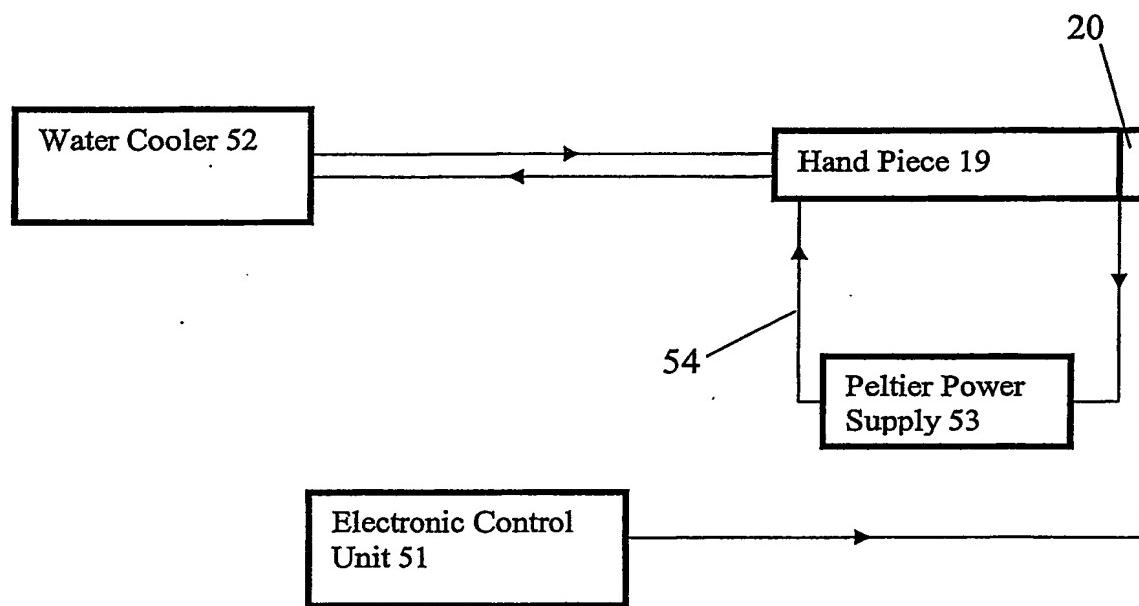


Fig 4

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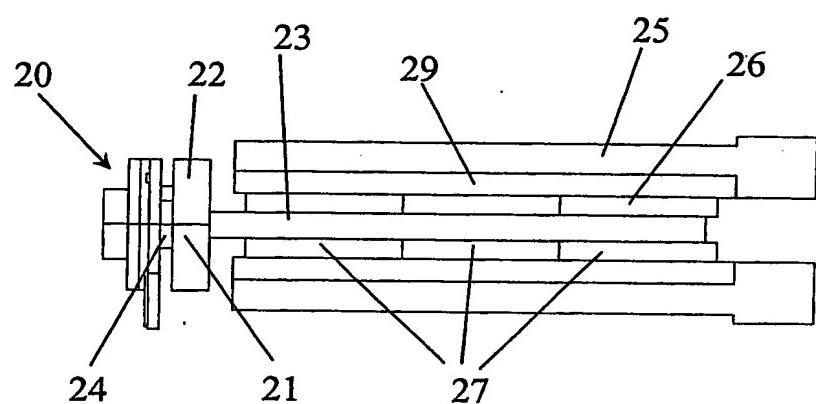


Fig 5a

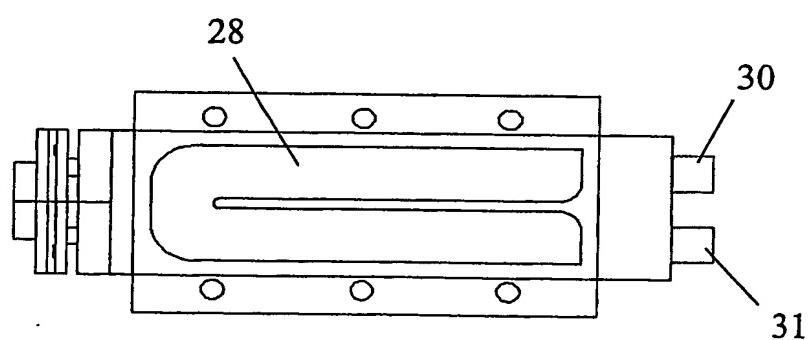


Fig 5b

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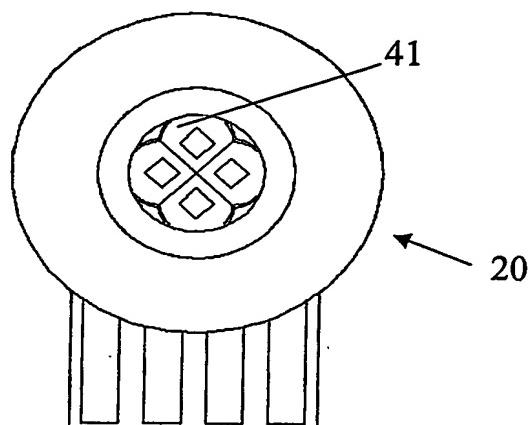


Fig 6a

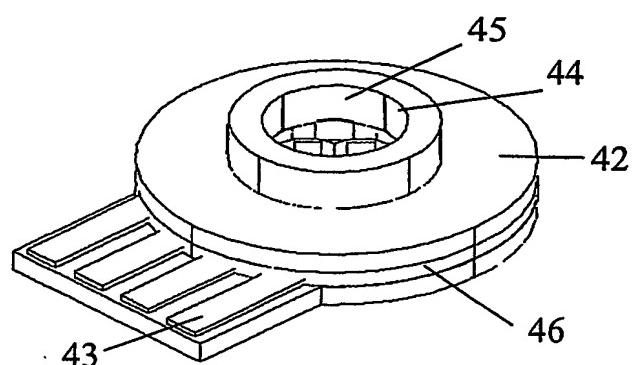


Fig 6b

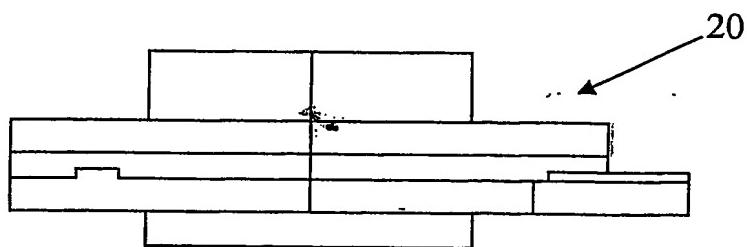


Fig 6c

Method and device for treatment of skin conditions

BACKGROUND OF THE INVENTION

5 **Field of the Invention**

The present invention relates to a method and apparatus for the treatment of a skin condition or for improving the cosmetic appearance of skin. In particular, the invention relates to a method and apparatus for the treatment of Acne Vulgaris.

10 Acne Vulgaris is a skin condition which affects almost 100% of the population at some point in their lives. It is a condition of the sebaceous follicles (pores) and can lead to lesions on the skin, primarily on the face, shoulders and back. The symptoms of Acne Vulgaris, and of other similar skin 15 conditions, can be unsightly and undesirable cosmetically.

Acne Vulgaris is caused by a number of factors, of which the most significant are believed to be: excessive hormone production (especially androgens), excessive sebum production (sebum is an oily substance produced by the sebaceous glands to keep the skin 20 soft, pliable and waterproof), excessive dead cell shedding, the presence of bacteria (particularly *Propionibacterium acnes*) in the sebaceous follicles and the body's inflammatory response (chemotaxis).

The process starts when dead skin cells and the oily 25 substance sebum combine to block the skin's sebaceous follicles. The dead skin and sebum form a plug which traps oil and bacteria within the sebaceous follicles. The sebaceous follicle begins to swell as the skin continues its normal oil production. Normal skin bacteria *Propionibacterium acnes* multiply rapidly in 30 the clogged pore. The multiplication of the bacteria produces substances which cause inflammation in the follicle and surrounding skin. The body's response is to send white blood cells to the inflamed areas.

The lesions range in severity and can be defined as comedones, papules, nodules, pustules and cysts. Comedones are sebaceous follicles that have become blocked. Papules are small (less than 5mm) solid lesions slightly above the surface of the skin. Nodules are larger papules (greater than 5mm). Pustules are dome shaped fragile lesions typically containing a mixture of white blood cells, dead cells and bacteria. Cysts are similar to pustules but are larger and are severely inflamed and often lead to scarring.

10 Various drug treatments are known to be at least partially effective in preventing Acne Vulgaris.

Description of the Related Art

A treatment for Acne Vulgaris using light radiation is disclosed in GB 2 368 020. In the embodiments disclosed, radiation is provided at specific energy densities and wavelengths in order to cause photo-chemical and photo-thermal reactions in the skin. The photo-chemical reaction leads to a partial disabling or eradication of a cause of the skin condition while the photo-thermal reaction increases collagen production, thereby helping to reduce the risk of scarring.

The method disclosed in GB 2 368 020 requires the provision of relatively high doses of radiation (0.5Jcm^{-2} to 5Jcm^{-2}) in short periods of time (10 μs to 100ms) in order to produce the photo-thermal effects in the skin. Providing these high energy levels over short periods of time requires high power lasers. These are expensive to manufacture and operators may be required to have specialist training and knowledge to use them safely and effectively.

It is an object of the invention to provide an apparatus for the treatment of a skin condition that is relatively inexpensive and/or simple to operate and/or to provide a method for the treatment of a skin condition that is relatively inexpensive
5 and/or simple to carry out.

According to an aspect of the invention there is provided a method for improving the appearance of a region of skin by means of conducting the steps of providing an illuminating device, and operating the illuminating device to direct light radiation on to
10 the region of skin, wherein during a period of at least 100ms, said region receives light energy from the illuminating device of at least 0.01Jcm^{-2} , the light energy so delivered in any given period of $10\mu\text{s}$ is less than 0.5 Jcm^{-2} , and the light energy so delivered in any given period of 100ms is less than 5 Jcm^{-2} .

15 According to another aspect of the invention there is provided a method for treating the skin condition Acne Vulgaris, the method including the steps of providing one or more light emitting diodes, and operating said one or more light emitting diodes to direct light radiation on to a region of skin affected
20 by Acne Vulgaris, wherein during a single dose lasting at least 100ms, said region receives light energy from said one or more light emitting diodes of at least 0.01Jcm^{-2} , and the light energy causes a photochemical reaction in said region that stimulates the production of free radicals that react with, and at least
25 partially disable or destroy, bacteria that contribute to the symptoms of Acne Vulgaris.

According to yet another aspect of the invention, there is provided a method of improving the cosmetic appearance of a region of the skin of a mammal comprising the steps of providing
30 an illuminating device, and operating the illuminating device to direct light radiation on to the region of skin, wherein during a

period of at least 100ms, said region receives light energy from the illuminating device of at least 0.01Jcm^{-2} , the light energy so delivered in any given period of $10\mu\text{s}$ is less than 0.5 Jcm^{-2} , and the light energy so delivered in any given period of 100ms is 5 less than 5 Jcm^{-2} .

The light energy so delivered advantageously causes a photochemical reaction within the skin. Thus the cosmetic appearance of the affected area of skin may be improved.

By providing direct light radiation for a longer period of 10 time than prior art methods, similar photon or energy densities can be delivered but at much lower power densities or energy flux densities, thereby reducing the likelihood of any adverse reactions of the skin to the radiation, for example, causing photo-mechanical effects (explosive expansion of the tissue) or 15 photo-thermal effects (rapid heating of the tissue). In addition, providing radiation at lower power means the radiation is less likely to induce erythema (redness of the skin). Advantageously, the method of the invention is performed without any active pre-cooling of the skin immediately before treatment. Some prior art 20 methods utilising higher light intensities than in the present invention cause the target area to be heated so quickly that heat cannot be effectively dissipated by means of the vascular system, such methods thus requiring cooling of the skin before treatment 25 to prevent undesirable effects associated with the over-heating of the skin.

Preferably, during said period of at least 100ms, said region receives light energy from the illuminating device of less than 10kJcm^{-2} , and more preferably less than 1kJcm^{-2} . Preferably, during said period of at least 100ms, no more than 100Jcm^{-2} of 30 light energy is delivered over any given period of 1 minute. The method may be so performed that during said period of at least

100ms, no more than 100Jcm^{-2} of light energy is delivered over any given period of 10 minutes. The light energy so delivered in any given period of 1ms is preferably less than 1Jcm^{-2} . The light energy so delivered in any given period of 10ms is 5 preferably less than 1Jcm^{-2} . The light energy so delivered in any given period of $500\mu\text{s}$ is preferably less than 1Jcm^{-2} . Said period is preferably less than 10 hours.

The light energy so delivered in any given period of $10\mu\text{s}$ is preferably less than 50mJcm^{-2} , more preferably is less than 10 10mJcm^{-2} , and yet more preferably is less than 5mJcm^{-2} . The light energy so delivered in any given period of $10\mu\text{s}$ may be less than 1mJcm^{-2} .

The lower power requirements of the present invention compared to prior art methods means that LEDs (Light Emitting Diodes) can be used rather than lasers. At low powers, these 15 tend to be cheaper and less complicated than equivalent laser systems. Also the use of laser devices is in many countries subject to strict regulations. The illuminating device thus advantageously includes a plurality of LEDs, for example, 20 including a plurality of LEDs grouped together to form an array. A single LED may be used. For example, the LEDs may form a 1 dimensional line array or a 2 dimensional array suitable for illumination of larger areas such as the face or back.

Advantageously, the LEDs could be grouped to form a face mask 25 under which a user (i.e. a person whose skin is affected by a skin condition) could be positioned. Using such a face mask system enables a substantially uniform dose of radiation to be applied to the whole face within a short amount of time, for example in a period as short as 30 seconds. In contrast, it can 30 take up to 30 minutes for an operator to treat a whole face using the single spot applicator system. In both cases, the skin would

receive a similar dose of light radiation to induce a similar photochemical response.

The method may be utilised in a method of therapeutic treatment on the human body. The method may be in the form of a
5 method of cosmetic treatment.

The method is preferably for the cosmetic treatment of Acne Vulgaris. The method may be in the form of a method for the cosmetic treatment of Rosacea.

The "skin" referred to may be the skin of a mammalian animal,
10 preferably human. The method is preferably non-surgical. For example, the illuminating device is preferably arranged and configured so as to be unable to be operated at sufficiently high power to be considered a surgical device necessitating a skilled operator, such as a surgeon. The illuminating device may thus be
15 arranged to be intrinsically more safe and less complex to operate and manufacture than the pulsed dye laser or apparatuses of the prior art.

Advantageously, a photo-chemical reaction is caused that disables or destroys, wholly or partially, the bacteria
20 Propionibacterium acnes, which, as described above, is one of the causes of Acne Vulgaris. Propionibacterium acnes is anaerobic and is harmed by the presence of oxygen. The photo-chemical reaction may be such that the symptoms of acne are, at least temporarily, reduced without necessarily permanently destroying
25 the agents, for example the bacteria, that contribute to the symptoms of a skin condition.

The photo-chemical reaction may take place in a substance as a result of that substance absorbing radiation within a range of particular wavelengths (the reaction being significantly slower
30 or non-existent outside the range). Preferably the wavelength of radiation used produces a photo-chemical reaction in a substance

(a chromophore, for example) of, on or in the skin that results in the production of free radicals (for example in the form of oxygen singlets) which thereafter may destroy the bacterium. The chromophore targeted is preferably porphyrin. Porphyrin is a naturally occurring substance produced by the bacteria Propionibacterium acnes. Porphyrin produces singlet oxygen when excited by light of a wavelength of around 585nm (yellow light) and also when excited by light of a wavelength of around 405nm (violet/near ultra-violet light light). Light at other wavelengths is also able to stimulate free-radical production.

Thus by exciting Porphyrin in the manner outlined above it is possible to disable or destroy the bacterium responsible for Acne Vulgaris in a pain-free, non-invasive and efficient manner. The method according to the present invention provides a means of destroying, at least partially, the bacteria that contributes to a skin condition but without needing to use high power lasers, which as mentioned above have various disadvantages.

The duration of the treatment or the length of the period during which light radiation is provided by the illuminating device may, for example, be between 100ms and 30 minutes, is preferably between 200ms and 10 seconds, is more preferably between 200ms and 3 seconds and is yet more preferably between 300ms and 2 seconds. The duration or period may alternatively or additionally be greater than 500ms. The delivery of light radiation may continuous during a single treatment or during said period. Alternatively, the delivery of light radiation may be pulsed during a single treatment or during said period.

The duration of the light radiation is preferably substantially greater than the thermal relaxation time of the microvascular system near the area of skin affected by the skin condition. Thus,..the photo-thermal response taught in GB2368020

is not significant in the proposed method due to the relatively low dose of light radiation energy supplied within the hundreds of micro-seconds timescale (of the same order of time as that of the microvascular thermal relaxation timescale).

5 The energy density of the illuminating radiation delivered may, for example, be between 0.01 and 100 Jcm^{-2} , is preferably between 0.1 and 10 Jcm^{-2} , is more preferably between 0.5 and 3 Jcm^{-2} and is even more preferably between 1 and 3 Jcm^{-2} . The energy density may be less than 2 Jcm^{-2} . Lower energy densities
10 are preferable at longer durations.

The dominant wavelength of the illuminating radiation is preferably pre-determined. The radiation may, for example, include radiation having a wavelength of between 350nm and 1500nm , or more preferably between 350nm and 1000nm . The wavelength is
15 preferably between 350nm and 700nm , more preferably between 570nm and 600nm and is even more preferably between 580nm and 590nm . The illuminating radiation may include radiation substantially concentrated around the wavelength of yellow light (585nm). The radiation may include radiation having a wavelength of between
20 350nm and 450nm , or more preferably between 390nm and 420nm . The illuminating radiation may include radiation substantially concentrated around the wavelength of violet/near ultra-violet light light (405nm). In accordance with the invention,
25 especially insofar as the treatment for Acne Vulgaris is concerned, the radiation may be chosen to correspond to a photosensitizer such as for example porphyrin in skin tissue. The wavelength of the light radiation may be chosen to correspond with a wavelength suitable for targeting the porphyrin in the skin layers at a depth suitable to ensure that singlet oxygen is
30 released which affects the propriionibacterium Acnes without significantly affecting other tissues.

It is especially advantageous to use radiation at one or more wavelengths that correspond to one or more of the peaks of the porphyrin absorption curve.

The illuminating radiation may be provided to an area of the
5 affected skin of between 12 and 200mm², for example, to a spot size of diameter 4-16mm. The area may be less than 100mm². A greater area may be treated however. For example an area of up to 0.1m² or even up to 0.5m² might be treated simultaneously.

Preferably the illuminating radiation delivered has a peak
10 optical power level of less than 100Wcm⁻² and more preferably less than 10W cm⁻². The illuminating radiation preferably provides a peak optical output power level of between 1 and 5Wcm⁻².

The light energy so delivered by the illuminating device may
15 cause a photochemical reaction within the affected skin thereby stimulating the production of free-radicals, which react with, and at least partially disable or destroy, agents causing the skin condition.

A low power spot or line treatment may be used to "top up"
20 the higher dose treatment described above. The top up treatment may for example be provided at lower powers than the higher dose treatment and over longer periods of time (for example, overnight). Such a low power treatment might be particularly well suited to use of the illuminating device in the home.

25 The method is preferably performed such that the distance between the illuminating device and the surface onto which the radiation is delivered is less than 1000mm, and is preferably less than 100mm. The distance of separation may be less than 50mm. The illuminating device and the surface may be directly adjacent to each other and may for example touch when radiation
30 is being delivered.

According to another aspect of the invention there is also provided an apparatus for the treatment of a skin condition comprising an illuminating device, and a control unit for controlling the operation of the illuminating device, wherein the 5 illuminating device is so arranged and configured that it is able in use to emit light radiation of an energy and wavelength profile sufficient to cause a photochemical reaction within an area of skin affected by a skin condition, which reaction would result in agents causing the skin condition being 10 at least partially disabled or destroyed, and the control unit and illuminating device are so arranged and configured that the control unit is able in use to cause the illuminating device to direct light radiation on to an area within a distance of no more than 1000mm from the illuminating device such that: the light 15 energy received at said area during a period of at least 100ms is at least 0.01Jcm^{-2} , the light energy received at said area in any given period of $10\mu\text{s}$ is less than 0.5 Jcm^{-2} , and the light energy so delivered in any given period of 100ms is less than 5 Jcm^{-2} , whereby the apparatus may be used to treat the skin condition.

According to a further aspect of the invention there is also provided an apparatus for the treatment of Acne Vulgaris comprising one or more light emitting diodes, and a microprocessor for controlling the operation of said one or more light emitting diodes, wherein said microprocessor and said one 25 or more light emitting diodes are so arranged and configured that said one or more light emitting diodes are able in use to deliver a dose of light radiation onto a surface during a period of at least 100ms, such that the surface receives during said dose light energy of at least 0.01Jcm^{-2} , the light so delivered 30 including radiation having a wavelength in the range of 350nm and 700nm, whereby the apparatus may be used to treat a region of

skin affected by the condition Acne Vulgaris by causing a photochemical reaction in said region that stimulates the production of free radicals that react with, and at least partially disable or destroy, bacteria that contribute to the 5 symptoms of Acne Vulgaris.

Further optional or preferred features of the apparatus according to either or both of the above-mentioned aspects of the invention are described below.

The apparatus may alternatively or additionally be suitable 10 for improving the cosmetic appearance of the skin of a mammal, for example a human being.

The illuminating device of the apparatus of the invention may be so arranged and configured that it is able, when being used to direct light onto the skin, to emit light radiation of an 15 energy and wavelength profile sufficient to cause a photochemical reaction within an area of the skin being targeted. The photochemical reaction may be caused in such a way that it partially disables or destroys agents in the skin that are causing the cosmetic appearance of the skin to be worsened.

20 The illuminating device preferably comprises one or more light emitting semiconductor devices. The or each semiconductor device may be in the form of a diode. The illuminating device may for example comprise one or more LEDs. LEDs are, advantageously relatively inexpensive and simple to operate in comparison to lasers. Laser diodes may additionally or 25 alternatively be used. Conveniently, the illuminating device is in the form of a device, for example comprising at least one semiconductor device that in use acts as the active light emitting element(s), that has a power input requirement of less than 500W, and preferably less than 100W, per individual 30 semiconductor device.

The control unit and illuminating device of the apparatus may be so configured and arranged that the control unit is able in use to cause the illuminating device to deliver light energy of between 0.01 and 100 Jcm^{-2} to said area during a period of
5 between 200ms and 3 seconds, or more preferably during a period of between 300ms and 2 seconds. Of course, the control unit and illuminating device may be arranged to emit radiation during a single treatment over a longer period of time, so that during a single treatment more than 100 Jcm^{-2} is delivered over a period
10 of greater than 3 seconds. A single treatment might last as long as up to 10 hours. Such a treatment might for example be provided overnight. Preferably, the control unit and illuminating device of the apparatus are so configured and arranged that less than 100 Jcm^{-2} of light energy is delivered
15 during any period of 3 seconds.

The control unit and illuminating device may be so configured and arranged that the illuminating device delivers pulsed light radiation during a single treatment. Alternatively, the control unit and illuminating device may be so configured and
20 arranged that the illuminating device delivers continuous light radiation during a single treatment. The apparatus may be so configured to be able to deliver either continuous or pulsed radiation at the choice of the user.

The control unit and illuminating device of the apparatus
25 may be so configured and arranged that the control unit is able in use to cause the illuminating device to deliver light energy of between 0.5 Jcm^{-2} and 3 Jcm^{-2} to said area during a period of between 100ms and 100 seconds. The control unit and illuminating device may be so configured and arranged that the control unit is
30 able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being

provided over a period of between 200ms and 10 seconds (or more preferably between 200ms and 3 seconds) and the energy of the light radiation delivered during the single dose being greater than 0.1 Jcm^{-2} and being equal to $T_1 \times P_1$, where T_1 = the length in time of the single dose and P_1 has the units of optical power density (power per unit area) and satisfies $0.2 \text{ Wcm}^{-2} < P_1 < 20 \text{ Wcm}^{-2}$.

The apparatus may be in the form of a top up apparatus allowing lower levels of light energy to be delivered. For example, the control unit and illuminating device may be so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 300ms and 10 seconds (or more preferably between 300ms and 3 seconds) and the energy of the light radiation delivered during the single dose being equal to $T_2 \times P_2$, where T_2 = the length in time of the single dose and P_2 has the units of optical power density (power per unit area) and satisfies $0.01 \text{ Wcm}^{-2} < P_2 < 1 \text{ Wcm}^{-2}$. P_2 may satisfy the condition $0.1 \text{ Wcm}^{-2} < P_2 < 0.5 \text{ Wcm}^{-2}$.

The apparatus may be so configured and arranged that it is suitable for treatment of relatively small areas at a time. For example, the apparatus may be so configured and arranged that, during a single dose of light radiation, an area of skin of between 12 and 200mm² is treated.

The apparatus may be so configured and arranged that it is suitable for lower power operation over longer periods of time. For example, the control unit and illuminating device may be so configured and arranged that the control unit is able in use to deliver, during a single treatment lasting between 300ms and 10 hours (more preferably between 10 seconds and 8 hours), light

radiation to an area of skin, the energy of the light radiation delivered during the single treatment being greater than 0.1 Jcm^{-2} and being equal to $T_3 \times P_3$, where T_3 = the length in time of the single treatment and P_3 has the units of optical power density (power per unit area) and satisfies $0.5\text{mWcm}^{-2} < P_3 < 500\text{mWcm}^{-2}$.
5 The longer treatment may last for at least 30 seconds, preferably lasts for at least 10 minutes and more preferably lasts for at least an hour.

The apparatus may be so configured and arranged that it is
10 suitable for treatment of relatively large areas at a time. For example, the apparatus may be so configured and arranged that, during a single treatment, an area of skin of between 0.003m^2 and 0.5m^2 is treated. Such an apparatus is preferably arranged such that the energy of the light radiation delivered during a single
15 treatment is equal to $T_3 \times P_3$, where T_3 = the length in time of the single treatment and P_3 has the units of optical power density (power per unit area) and satisfies $0.5\text{mWcm}^{-2} < P_3 < 500\text{mWcm}^{-2}$.

The illuminating device is preferably arranged to provide
20 light radiation including radiation having a wavelength of between 350nm and 1500nm. The illuminating device is preferably arranged to emit radiation at a wavelength between 350nm and 1000, more preferably between 350nm and 700nm. The illuminating device is preferably arranged to provide light radiation including
25 radiation having a wavelength between 570nm and 600nm. The illuminating device may alternatively or additionally be arranged to provide light radiation of a wavelength between 390nm and 420nm, and preferably includes light radiation having a wavelength of about 405nm. The Porphyrin activation spectrum has
30 peaks at both about 585nm and 405nm. Providing light radiation including light having a wavelength between 390nm and 420nm and

including light having a wavelength between 570nm and 600nm is considered to be particularly advantageous as such a combination may activate Porphyrin at different depths in the skin tissue.

Also, it is believed that red light (of a wavelength between 5 630nm and 680nm) may aid in the wound healing process.

The illuminating device is preferably arranged to provide light radiation having a peak power level of less than 100Wcm^{-2} . More preferably, the illuminating device is preferably arranged to provide light radiation having a peak power level of less than 10 Wcm^{-2} . Even more preferably, the illuminating device is preferably arranged to provide light radiation having a peak power level of less than 5Wcm^{-2} . Advantageously, the peak power level is between about 1Wcm^{-2} and 5Wcm^{-2} . The peak power level may be between about 1Wcm^{-2} and 3Wcm^{-2} .

15 The apparatus of the invention is advantageously so arranged that the apparatus may be used to treat the skin of a patient without the need to pre-cool the skin before treatment.

20 The apparatus may include cooling means for controlling the temperature of the illuminating device. The control unit is preferably arranged to control operation of any such cooling means. The control unit may conveniently comprise a suitably pre-programmed microprocessor. The cooling means may include a Peltier device. The cooling means may additionally or alternatively operate by utilising liquid coolant.

25 Above, mention is made of light energy causing a photochemical reaction within the skin. In order to cause a photochemical reaction in the skin, it is believed that the extent/amount of the photochemical reaction depends primarily on the amount of light (i.e. number of photons) received per unit 30 area and that the power of light used has a lesser effect. According to certain embodiments of the invention, it is

preferred for the light energy to be delivered over a relatively long period of time. According to certain other embodiments of the invention, it is preferred for the light energy to be delivered over a relatively short time without exceeding a given 5 power level that might cause undesirable effects resulting from heating of the skin. Thus according to some aspects of the invention it is preferred to have as high a power output as is reasonably possible without exceeding a maximum power output, above which there would be a risk of causing such undesirable 10 effects. It is considered especially advantageous that the present invention is able to provide an apparatus that utilises semiconductor light emitting devices (such as LEDs or laser diodes) that are able to operate at such power levels.

In accordance with the present invention there is also 15 provided a use of said apparatus including illuminating a surface within a distance of no more than 1000mm from the illuminating device with radiation of an energy such that an area of at least 12mm² receives energy from the illuminating device during a period of at least 100ms of at least 0.01Jcm⁻², the radiation 20 including radiation having a wavelength of between 350 and 700nm (preferably including radiation having a wavelength of between 570 nm and 600 nm and/or of between 390nm and 420nm), the energy received from the illuminating device at said area in any given period of 10μs being less than 0.5 Jcm⁻², and the energy received 25 from the illuminating device in any given period of 100ms being less than 5 Jcm⁻². Said use is advantageously, but not necessarily, performed to treat a skin condition on the skin of a human. The use of the apparatus may for example be in the form of performing the method of the invention. The use of the 30 apparatus may for example be in the form of testing and/or

demonstrating the apparatus on a surface that is, for example, not in the form of the skin of a living animal or human.

It will be appreciated that the method of the invention may include use of the apparatus of the invention and that the apparatus of the invention may be arranged and configured to be suitable for performing the method of the invention. Thus, features described with reference to the method of the invention may be incorporated in the apparatus of the invention. Also, features described with reference to the apparatus of the invention may be incorporated in the method of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention will now be described by way of example with reference to the following schematic drawings of which:

- Figure 1 shows an apparatus according to a first embodiment including a control unit and an illuminating device being used to treat the skin of a patient;
- Figure 2 shows the control unit and illuminating device of the apparatus shown in Figure 1;
- Figure 3 shows in greater detail the illuminating device of the apparatus shown in Figure 1;
- Figure 4 shows a block diagram illustrating the components of an apparatus according to a second embodiment of the invention;
- Figure 5a is a sectional side view of a hand-piece of the apparatus according to the second embodiment;
- Figure 5b is a plan view of the hand-piece shown in Figure 5a;

Figure 6a is an end-on view of the hand-piece of Figure 5a showing an LED assembly;

Figure 6b is a perspective view of the LED assembly shown in Figure 6a; and

5 Figure 6c is a side view of the LED assembly shown in Figure 6a.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

10 Figure 1 shows an apparatus 10 according to a first embodiment of the present invention for the treatment of a skin condition such as acne by directing light radiation 12 onto the skin 11 of a human patient. The skin to be treated in this embodiment is an area of skin on the face including a spot having 15 a diameter about 6mm. The apparatus 10, in this embodiment a hand-held battery powered unit, includes an illuminating device 1 and a control unit 9 linked thereto which controls the radiation emitted by the device 1. The housing of the apparatus 10 is elongate in shape and has a proximal end via which light is 20 emitted from the illuminating device 1. The overall length of the housing is about 15cm.

The apparatus 10, in use, is placed against the skin with the illuminating device 1 being positioned so as to direct radiation towards the affected area. Before operation the 25 apparatus is programmed to set the duration of the radiation and the power of radiation. In this embodiment the apparatus is set to provide a single pulse of light energy lasting 1 second that delivers 1.5 Jcm^{-2} to the 6mm diameter spot. The peak power output of the illuminating device 1 is below 5W/cm^{-2} . The energy 30 profile over time of the radiation delivered is such that the energy is continuously delivered during the 1 second pulse and is

such that during any period of $10\mu s$ the light energy delivered is less than 0.5 Jcm^{-2} and such that during any period of 100ms the light energy delivered is less than 5 Jcm^{-2} . The method of this embodiment relies solely on photochemical effects that occur 5 within the skin as is explained in further detail below. In general, it is preferable that the method of the invention is so performed that, and/or the apparatus of the invention is so arranged that in normal use, there is substantially no beneficial photo-thermal reaction caused within the skin.

10 The radiation received by the skin 11 causes a photochemical reaction in Porphyrin in the skin that releases singlet oxygen (a free radical), which then destroys at least some of the bacteria, which is one of the causes of the symptoms of acne. The radiation received is however well below the level at which 15 erythema may be induced. The radiation emitted by the illuminating device includes light having an intensity that peaks at a wavelength of about 585nm and includes components of light radiation having wavelengths in the range of 570-600nm. Such wavelengths are suitable for targeting the porphyrin in the skin 20 layers at a depth sufficient for causing the released reactive oxygen to affect the *Propionibacterium acnes* bacteria without significantly affecting other tissues.

The illuminating device includes a plurality of LEDs 7 arranged in a 2-D array 2 (shown schematically in Figure 2 as 25 LEDs arranged in a close-packed formation) connected to a lens arrangement (not shown) that focuses the radiation emitted by the LEDs, so that a concentrated source of light is provided. The device 1 is therefore suitable for "spot treatment" of skin condition (i.e. treating small areas one at a time). Figure 3 30 shows other components of the illuminating device 1, such other components being provided to cool the LEDs.

Referring to the Fig. 3, there is shown illuminating device (generally designated 1) comprising, in sequence, an LED diode array 2, a high thermal conductivity heat spreader layer 3, a Peltier type thermoelectric cooler 4 and a heat pipe arrangement 5 (including a distal condenser 6).

The heat spreader 3, thermoelectric cooler 4 and heat pipe arrangement 5 are provided to keep the operating temperature of the LEDs at a reduced level and therefore operating most efficiently. It is well-known that the efficiency of an LED increases with reduced operating temperature and in the case of LEDs operating at wavelengths between 550nm and 650nm this dependence on temperature is very high.

Heat flowing from the LED diode array 2 is spread over a larger area by the high conductivity spreader layer 3. This layer is typically only a few millimetres thick and provides rapid and highly efficient heat transfer away from the diode array 2. Heat then flows into the cold end of the thermoelectric Peltier cooler 4. The hot end of the thermoelectric Peltier cooler layer 4 is in heat transfer coupling with the heat pipe 5. The high thermal conductivity layer 3 includes a diamond material, which is laid down by means of a plasma/chemical vapour deposition method.

The Peltier cooler 4 includes a separate control means including associated drive circuitry which accurately controls, during use, the heat transfer away from the LED diode array 2 via the high thermal conductivity spreader layer 3. Accurate control of the driven Peltier thermoelectric cooler 4 (in combination with the provision of the high thermal conductivity heat spreader layer 3 and the downstream heat pipe cooling arrangement 5) provides for extremely efficient thermal management of the

apparatus, and in particular the diode array 2, which ensures consistency of the light output.

The heat pipe arrangement 5 includes a wick to direct fluid coolant (contained in the heat pipe arrangement 5) away from the 5 "hot zone" via capillary action, gravity or diffusion. The arrangement includes a fluid return system to return cooled fluid from the "cold zone" at the distal end of the apparatus, which is provided with a condenser 6. The condenser 6 is itself cooled by air cooling.

10 The treatment of Acne using this method has been / will be trialled on patients suffering from facial acne. The illuminating device used in these trials was in the form of a small spot illuminating device (as described above). During the trials, the radiation emitted during a single dose was about 15 1.5J/cm^2 for a 6mm spot size. Trials are also planned with the use of the illuminating device similar to that described above but being in the form of a larger 2-D array of such devices. Such an array of devices would for example be suitable for illumination and treatment of larger areas such as the face or 20 back. The results of the initial trials appear to demonstrate a beneficial effect on the skin conditions treated.

An alternative, and preferred, apparatus 18 for performing the above described method is illustrated by Figures 4 to 6c, which show an apparatus according to a second embodiment of the 25 invention.

Figure 4 shows a block diagram illustrating schematically the parts of the apparatus 18. The apparatus 18 includes a hand-piece 19 in which is housed an LED assembly 20 with an associated integral cooling system (not shown in Fig 4), a control unit 51 30 for controlling the hand-piece 19, a power supply 53 for the

integral cooling system and a separate water cooling system 52 that removes the heat from the integral cooling system.

The electronic control unit 51 provides the electrical power supply to each LED of the LED assembly in a controlled manner in 5 the form of continuous DC (direct current) power or pulsed power.

The water cooling system 52 comprises a submersible pump, a water reservoir and a radiator system. The radiator system receives heated water from the integral cooling system of the hand-piece 19. That water cools as it passes through the 10 radiator. The cooler water is then fed back to the integral cooling system of the hand piece 19. Heat exchange at the radiator is assisted by means of an air fan.

The power supply 53 for the integral cooling system unit incorporates a feedback loop 54 that assists in the cooling 15 method employed. The temperature of the LED assembly 20 is sensed and the power delivered to the cooling system is controlled to be dependent on the temperature so sensed in order to keep the temperature of the LED assembly at a pre-selected temperature. In this embodiment the pre-selected temperature is 20 -15 degrees Centigrade (258K).

Figure 5a shows a sectional side view of the hand piece 19 and Figure 5b shows a plan view of the hand piece 19. As mentioned above, the hand piece comprises an LED assembly 20, which is mounted at one end of the generally elongate hand piece 25 19, and an integral cooling system, which is housed in the main body of the hand piece. The cooling system comprises a heat spreader 21, a Peltier assembly 26 and a water-cooling unit 25. The overall length of the hand piece is about 15cm.

The heat spreader 21 consists of a disc 22, one side of 30 which is in thermal conductive contact with a heat sink of the LED assembly 20 and the other side of which is integrally formed

with and connected to one end of a flat plate 23. The heat spreader is made from copper (but could be made from or coated with any other material having a high thermal conductivity such as silver or diamond).

5 The Peltier assembly 26 comprises six Peltier cooling units 27 mounted three on each side of the flat plate 23, so that the cool side of each Peltier unit 27 is in contact with the plate 23 of the heat spreader 21.

The water cooling unit 25, which partially surrounds the
10 Peltier assembly, is in close thermal conductive contact with the hot side of each of the Peltier units 27 and, in use, removes heat from the Peltier assembly 26. The cooling unit 25 comprises two aluminium blocks, positioned on opposite sides of the hand piece 19. Figure 5b shows one of the blocks in plan view. The
15 block includes a duct 28 sealed by a sealing plates 29 disposed between the duct and the Peltier units 27. Relatively cool water from the separate water cooling system 52 passes into each duct 28 via an inlet port 30 and relatively warmer water is passed out of the duct 28 via an outlet port 31 and flows back to the
20 separate water cooling system 52. The water is circulated by means of the pump of the separate water cooling system 52.

Thus, during use, the LED assembly is cooled by means of the integral cooling system and in particular by the Peltier assembly, and the Peltier assembly is cooled by means of the water cooling
25 unit 25 and the separate water cooling system 52.

The LED assembly is shown in more details in Figures 6a to 6c. The LED assembly comprises four standard LEDs, each of which having been modified by shaving or machining away a part of the housing of the LED to form two adjacent perpendicular faces. A
30 shaved face of one LED abuts a shaved face of an adjacent LED, the four LEDs thereby forming an array 41 in the general shape of

a cloverleaf. By removing material from the LED housing in this way, the respective dice of the LEDs are brought into closer proximity than would otherwise be possible.

Electrical connections are provided through a printed circuit board 43, which is mounted on the flange defined by the LED assembly 20. The light output side of the LED array 41 is surrounded by a cylindrical tube, the interior of which forms a polished reflecting surface 42 which acts to direct the light from the LED array 41 through the circular aperture formed by the open end of the tube 44.

The reflecting surface 42 of the tube is so shaped as to transmit light from the LED array 41 to the circular aperture in as efficient a manner as possible. The wall of the tube 44 is arranged at such an angle that an optimum amount of light is coupled out of the LED array to the circular aperture, whilst minimizing the aperture diameter so as to achieve high optical power densities. The interior of the tube is filled with a soft transparent gel, which prevents condensation on the LED dice. The type of gel used preferably does not discolour with age or temperature cycling is preferably flexible and able to conduct some heat away from the LEDs. The gel, having a refractive index of about 1.5, provides a refractive index step between the semiconductor LED surface layers (refractive index about 3) and the air (refractive index of 1.00). This refractive index step improves the optical extraction by increasing the photon escape probability from within the LED die. Such an optical gel is available from Nye Lubricants of Fairhaven, Massachusetts, USA. (It is believed that Nye Lubricants is a name under which the company known, or formerly known, as William F. Nye, Inc. of New Bedford, Massachusetts, or a related company thereof, trades).

In the region of the free end of the tube, the gel is covered by a layer of hardened transparent epoxy resin that provides optical lensing, physical protection and some refractive index matching between the semiconductor dice and the outside 5 atmosphere. An insulating layer 46 is placed between the printed circuit board 43 and the reflector 42.

The method of treatment described above with reference to the first embodiment may also be performed by the apparatus according to this second embodiment. The wavelengths and 10 intensity of light emitted by the above-described apparatus are the same as described with reference to the first described embodiment. However, the apparatus of the second embodiment has the advantage that, if desired, the apparatus is able to be used to produce higher levels of light intensity. This advantage may 15 be achieved by lowering the operating temperature of the LED array still further, thus increasing the LED efficiency and also allowing the device to be driven to currents higher than that that would be possible at the higher operating temperatures of the LED array. In devices of the prior art, the current flowing 20 through an LED array causes a temperature rise in the LEDs. The maximum temperature at which the LED will work properly depends on the packaging and wiring of the LED die. Thus, if the base temperature of the LED heat sink is lowered then more current may be passed through the LED before the maximum allowable LED 25 temperature is reached. Of course, there may be other limitations, such as maximum permissible current, but such limitations can be overcome with changes to the packaging of the LED array.

It will be appreciated that various modifications may be 30 made to the above-described embodiments of the invention without departing from the spirit of the invention. For example, the

illuminating device used may be in the form of any illuminating device able to produce controlled doses of radiation at appropriate energy levels and wavelengths, without exceeding certain power levels. For example, the illuminating device may 5 be in the form of a line of a plurality of the illuminating devices described above (a "line treatment") or could be in the form of the 2-D array of devices as proposed for use in the trials (a "wide area treatment"). There may also be provided a lower fluence device for spot treatment or for line treatment 10 that can be used to "top-up" the higher dosage spot treatment described above. Such a low fluence device would be particularly suitable for home-use.

In the embodiments described above, the wavelength of radiation used is in the range 570-600nm. However, other 15 embodiments are envisaged that target other peaks in the porphyrin absorption within the skin tissue. Thus, for example light radiation having wavelengths in the violet/near ultra-violet light, blue, green and red wavelength bands could also be used, either individually, or in various combinations. The light 20 could be emitted from a single apparatus (possibly from a single illuminating device) or by separate apparatuses. The control unit would of course control the relative levels of light for the different colours to deliver differing amounts of reactive light at different depths in the skin - thereby tailoring the proposed 25 treatment dependent on the depth of infection by the *Propionibacterium acnes* bacteria.

The spreader of the second embodiment could also be in the form of a shaped heat pipe and could be formed of diamond coated metal. With reference to the second embodiment, rather than 30 modifying the packages of commercially available LEDs by machining their sides, the LED dice could be mounted on a header

specifically designed for the purpose. Also, the gel inside the reflector tube could be replaced by a number of gels with different refractive indices so as to shape the output light beam in some desired form, for example to produce a narrower beam than
5 would otherwise be the case. The water cooling system of the second embodiment could of course use a liquid coolant other than water.

CLAIMS

1. A method for improving the appearance of a region of skin by means of conducting the steps of

5 providing an illuminating device, and
operating the illuminating device to direct light radiation on to the region of skin, wherein
during a period of at least 100ms, said region receives light energy from the illuminating device of at least 0.01Jcm^{-2} ,
10 the light energy so delivered in any given period of $10\mu\text{s}$ is less than 0.5 Jcm^{-2} , and
the light energy so delivered in any given period of 100ms is less than 5 Jcm^{-2} .

15 2. A method according to claim 1, wherein the method is conducted for the purpose of treating a skin condition and wherein

20 the illuminating device is operated to direct light radiation on to an area of skin affected by the skin condition, and

the light energy so delivered causes a photochemical reaction within the skin affected by the skin condition, the reaction at least partially disabling or destroying agents contributing to the symptoms of the skin condition.

25 3. A method according to claim 2, wherein the skin condition is Acne Vulgaris.

30 4. A method according to claim 2, wherein the agents are bacteria.

5. A method according to claim 2, wherein said photochemical reaction stimulates the production of free-radicals, which then react with, and at least partially disable or destroy, agents causing the skin condition.

5

6. A method according to claim 1, wherein the illuminating device comprises one or more light emitting semiconductor devices.

10 7. A method according to claim 6, wherein the or each semiconductor device is in the form of a diode.

15 8. A method according to claim 1, wherein the illuminating device delivers a dose of light radiation to an area of skin, the dose being provided over a period of between 200ms and 10 seconds and the energy of the light radiation delivered during the dose being greater than 0.1 Jcm^{-2} and being equal to $T_1 \times P_1$, where T_1 = the length in time of the dose and P_1 has the units of optical power density (power per unit area) and satisfies $0.2\text{Wcm}^{-2} < P_1 < 20\text{Wcm}^{-2}$.

20

25 9. A method according to claim 1, wherein the illuminating device delivers a dose of light radiation to an area of skin, the dose being provided over a period of between 200ms and 10 seconds and the energy of the light radiation delivered during the dose being equal to $T_2 \times P_2$, where T_2 = the length in time of the dose and P_2 has the units of optical power density (power per unit area) and satisfies $0.01\text{Wcm}^{-2} < P_2 < 1\text{Wcm}^{-2}$.

30 10. A method according to claim 8 or claim 9, wherein said region of skin has a surface area of between 12 and 200mm².

11. A method according to claim 1, wherein the illuminating device delivers a dose of light radiation to an area of skin, the dose being provided over a period of between 300ms and 10 hours, the energy of the light radiation delivered during the dose being
5 greater than 0.1 Jcm^{-2} and being equal to $T_3 \times P_3$, where T_3 = the length in time of the dose and P_3 has the units of optical power density (power per unit area) and satisfies $0.5\text{mWcm}^{-2} < P_3 < 500\text{mWcm}^{-2}$.
- 10 12. A method according to claim 11, wherein said region of skin has a surface area of between 0.003 and 0.5m^2 .
13. A method according to claim 1, wherein the illuminating device provides light radiation including radiation having a
15 wavelength between 570nm and 600nm.
14. A method according to claim 1 or claim 13, wherein the illuminating device provides light radiation including radiation having a wavelength between 390nm and 420nm.
- 20 15. A method for treating the skin condition Acne Vulgaris, the method including the steps of
providing one or more light emitting diodes, and
operating said one or more light emitting diodes to direct
25 light radiation on to a region of skin affected by Acne Vulgaris, wherein
during a single dose lasting at least 100ms, said region receives light energy from said one or more light emitting diodes of at least 0.01Jcm^{-2} ,
- 30 and

the light energy causes a photochemical reaction in said region that stimulates the production of free radicals that react with, and at least partially disable or destroy, bacteria that contribute to the symptoms of Acne Vulgaris.

5

16. A method according to claim 15, wherein

the light energy so delivered in any given period of $10\mu\text{s}$ is less than 0.5 Jcm^{-2} , and

10 the light energy so delivered in any given period of 100ms is less than 5 Jcm^{-2} .

17. A method according to claim 15, wherein the light energy so delivered during a single dose is insufficient to cause any significant photothermal reaction in said region.

15

18. A method according to claim 15, wherein the alleviation in the symptoms of Acne Vulgaris in said region caused by the light energy so delivered is substantially entirely due to free-radicals caused by said photochemical reaction.

20

19. An apparatus for the treatment of a skin condition comprising

an illuminating device, and

a control unit for controlling the operation of the

25 illuminating device, wherein

the illuminating device is so arranged and configured that it is able in use to emit light radiation of an energy and wavelength profile sufficient to cause a photochemical reaction within an area of skin affected by a skin condition, which

30 reaction would result in agents causing the skin condition being at least partially disabled or destroyed, and

the control unit and illuminating device are so arranged and configured that the control unit is able in use to cause the illuminating device to direct light radiation on to an area within a distance of no more than 1000mm from the illuminating

5 device such that:

the light energy received at said area during a period of at least 100ms is at least 0.01Jcm^{-2} ,

the light energy received at said area in any given period of $10\mu\text{s}$ is less than 0.5 Jcm^{-2} , and

10 the light energy so delivered in any given period of 100ms is less than 5 Jcm^{-2} , whereby

the apparatus may be used to treat the skin condition.

15 20. An apparatus according to claim 19, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 200ms and 10

20 seconds and the energy of the light radiation delivered during the single dose being greater than 0.1 Jcm^{-2} and being equal to $T_1 \times P_1$, where T_1 = the length in time of the single dose and P_1 has the units of optical power density (power per unit area) and satisfies $0.2\text{Wcm}^{-2} < P_1 < 20\text{Wcm}^{-2}$.

25

21. An apparatus according to claim 19, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 200ms and 10

30 seconds and the energy of the light radiation delivered during

the single dose being equal to $T_2 \times P_2$, where T_2 = the length in time of the single dose and P_2 has the units of optical power density (power per unit area) and satisfies $0.01\text{Wcm}^{-2} < P_2 < 1\text{Wcm}^{-2}$.

5

22. An apparatus according to claim 20 or claim 21, wherein the apparatus is so configured and arranged that, during a single dose of light radiation, an area of skin of between 12 and 200mm^2 is treated.

10

23. An apparatus according to claim 19, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to deliver, during a single treatment lasting between 300ms and 10 hours, light radiation to an area of skin, the energy of the light radiation delivered during the single treatment being greater than 0.1 Jcm^{-2} and being equal to $T_3 \times P_3$, where T_3 = the length in time of the single treatment and P_3 has the units of optical power density (power per unit area) and satisfies $0.5\text{mWcm}^{-2} < P_3 < 500\text{mWcm}^{-2}$.

15

24. An apparatus according to claim 23, wherein the apparatus is so configured and arranged that, during a single treatment, an area of skin of between 0.003 and 0.5m^2 is treated.

20

25. An apparatus according to claim 19, wherein the illuminating device is arranged to provide light radiation including radiation having a wavelength between 570nm and 600nm.

25

26. An apparatus according to claim 19 or claim 25, wherein the illuminating device is arranged to provide light radiation including radiation having a wavelength between 390nm and 420nm.

27. An apparatus according to claim 19, wherein the illuminating device comprises one or more light emitting semiconductor devices.

5 28. An apparatus according to claim 27, wherein the or each semiconductor device is in the form of a diode.

10 29. An apparatus for the treatment of Acne Vulgaris comprising one or more light emitting diodes, and a microprocessor for controlling the operation of said one or more light emitting diodes, wherein
15 said microprocessor and said one or more light emitting diodes are so arranged and configured that said one or more light emitting diodes are able in use to deliver a dose of light radiation onto a surface during a period of at least 100ms, such that the surface receives during said dose light energy of at least 0.01Jcm^{-2} , the light so delivered including radiation having a wavelength in the range of 350nm and 700nm, whereby
20 the apparatus may be used to treat a region of skin affected by the condition Acne Vulgaris by causing a photochemical reaction in said region that stimulates the production of free radicals that react with, and at least partially disable or destroy, bacteria that contribute to the symptoms of Acne
25 Vulgaris.

30. An apparatus according to claim 29, wherein apparatus is so arranged that the light energy so delivered in any given period of $10\mu\text{s}$ is less than 0.5 Jcm^{-2} , and
the light energy so delivered in any given period of 100ms is less than 5 Jcm^{-2} .

ABSTRACT OF THE DISCLOSURE

A method and apparatus for improving the cosmetic appearance of a region of skin 11 affected by Acne Vulgaris, Rosacea or similar skin condition by means of directing light radiation 12 from an illuminating device 1 on to the skin 11. The apparatus 10 comprises a control unit 9 that operates one or more LEDs 7 (light emitting diodes) of the illuminating device 1. Each dose 15 of light radiation 12 lasts for at least 100ms, during which time the skin 11 receives light energy from the LED(s) 7, which causes a photochemical reaction that stimulates the production of free radicals (singlet oxygen) that react with, and at least partially disable or destroy, bacteria that contribute to the symptoms of the skin condition. The light energy directed on to the skin 11 20 during any given period of $10\mu s$ is less than 0.5 Jcm^{-2} , and during any given period of 100ms is less than 5 Jcm^{-2} . Substantially no beneficial photo-thermal reaction occurs within the skin 11. Light having wavelengths around 405nm and/or 585nm is used. The duration of a single dose may be much longer than 100ms and can last up to 10 hours (for overnight treatment).

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